REMARKS

Applicants believe that all of the alleged bases for rejecting the present claims in this application set forth in the official action of July 23, 2002, have now been overcome. Thus, in view of the above-noted amendments to the specification and claims, and the Declaration under Rule 131 submitted herewith, it is believed that there are no longer any valid objections to the issuance of a patent based on these claims, and such action is therefore respectfully solicited.

Claims 84 and 86-92 have been rejected under 35 U.S.C. § 112, second paragraph. In response to the Examiner's objection to the word "based" in claim 84, this word has been deleted. However, the Examiner has also objected to the word "substantially" in claim 84. This rejection is respectfully traversed.

There is no legitimate basis for this rejection. Indeed, issued U.S. patents are replete with this very word, and for good reasons. It is, in fact, a necessary word to provide realistic protection for patentees. While it is clear from the present specification that water and the other specific solvents must be excluded from the claimed transdermal delivery systems, it is, of course, virtually impossible to exclude all water therefrom, for example. The present specification describes in detail the precise reasons why such liquids must be kept out of these products. In addition, it is also clear form the case law that language such as "substantially" is perfectly acceptable in such circumstances, and does not violate the provisions of § 112. *In re Mattison*, 509 F.2d 563, 184 U.S.P.Q. 484 (C.C.P.A. 1975) is a case where the Board's application of § 112 to the language "substantially increase the efficiency of the compound as a copper extractant" was reversed. In *Seattle Box Co., Inc. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 U.S.P.Q. 568 (Fed. Cir. 1984), later appeal 756 F.2d 1574, 225

U.S.P.Q. 357 (Fed. Cir. 1985), the court again confirmed the fact that use of "substantially equal to" was not indefinite. *See also Andrew Corp. v. Gabriel Elecs., Inc.*, 847 F.2d 819, 6 U.S.P.Q.2d 2010 (Fed. Cir. 1988). It is therefore respectfully requested that this objection be withdrawn.

Claim 92 has been rejected under 35 U.S.C. § 112, first paragraph. The Examiner contends that the specification is not reasonably enabling for water. The Examiner thus contends that the Markush group in claim 92 does not exclude water when the solvent excluded is the solvent meeting conditions (i) and (ii). However, in view of the above-noted amendment to claim 92 it is clear that this objection has now been overcome.

The disclosure has been objected to because of an obvious typographical error on page 11, line 27, which has now also been corrected, thus obviating this objection.

The final objection in this case is the rejection of claims 84 and 86-92 as being anticipated by Mantelle '022 under 35 U.S.C. § 102(e). The Examiner contends that Mantelle '022 teaches a transdermal comprising a liquid active and a polymer free of the same solvents claimed, citing DUROTAK-87-2852 and the polymer applicants specify. However, in view of the above-noted amendments and arguments, and the Supplemental Declaration under Rule 131 submitted herewith, it is clear that Mantelle '022 is not a proper reference against the claims in this application, and this rejection should also now be removed.

The enclosed Supplemental Declaration under Rule 131 clearly and unequivocally establishes that at a date prior to the earliest possible filing date of Mantelle '022 (namely, June 7, 1995), the present inventors invented and actually reduced to practice the subject matter of the pending claims herein.

The declaration clearly establishes, with corroboration, that the claimed transdermal delivery system for selegiline was actually reduced to practice. This reduction to practice included a transdermal patch having a non-aqueous solvent in connection with an acrylic adhesive polymer system and employing only solvents which were highly volatile, such as ethanol, which were removed during drying, but which excluded solvents that remained after drying, such as propylene glycol and the like. The reduction to practice thus employed the low molecular weight drug selegiline, which is a liquid at or about room temperature, along with a polymer system in which the entire system was substantially free of water, as well as being free of liquids which had a normal boiling point below processing temperatures for the patch, and equal to or greater than the normal boiling point of the selegiline itself.

Beginning at paragraph 9 of the enclosed Declaration, the specific steps in the reduction to practice of such selegiline patches are set forth in detail, and it is established beyond doubt that, prior to June 7, 1995, the inventors hereof reduced to practice a transdermal patch falling directly within the scope of claims 84 and 86-92.

It is therefore respectfully requested that the sole rejection remaining in this case over the Mantelle '022 patent under 35 U.S.C. § 102(e) be withdrawn. Furthermore, that being the case, there are no longer any valid objections to the issuance of a patent based upon these claims, and such action is therefore respectfully solicited. If, however, for any further reasons the Examiner still does not believe that such actions can be taken, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: November 4, 2002

Respectfully submitted,

By _____

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MARKED-UP COPY OF AMENDED SPECIFICATION PARAGRAPHS:

Amend the paragraph beginning on page 11, line 24, and ending on page 12, line 5, as follows:

Applicants have also discovered that the traditional bench-top methods of gauging the performance of such adhesives are unreliable with particularly highly plasticizing drugs like selegiline. Therefore while tests like shear strength, peel tests from a ~~steal~~ steel plate and tack tests may eliminate certain candidates, they will not reliably identify successful candidates. Instead, it was discovered that the acrylic polymeric adhesives that worked the best in these application all have similar compositions. Generally, they include a C_4-C_{12} alkyl acrylate, a lower alkyl acrylate (C_1-C_4) hardening monomer such as methyl acrylate and a functionalizing monomer such as acrylic acid which facilities crosslinking. A crosslinking agent is also often useful.

MARKED-UP COPY OF AMENDED CLAIMS:

84. (FOUR TIMES AMENDED) ~~A~~ transdermal delivery system consisting essentially of a blend of:

(a) one or more hydrophobic ~~acrylic based~~ acrylic polymers; and

(b) a therapeutically effective amount of one or more drugs, at least one of which is of low molecular weight and liquid at or about room temperatures,

wherein said system is substantially free of water and liquids having a normal boiling point (i) below processing temperatures and (ii) equal to or greater than the normal boiling points of the low molecular weight drugs.

92. (AMENDED) A transdermal delivery system consisting essentially of a blend of:

(a) an acrylic-based polymer; and

(b) a therapeutically effective amount of a drug having a low molecular weight and being a liquid at or about room temperatures, wherein said system is substantially ~~free~~ of ~~solvents selected from the group consisting of~~ water and liquids having a normal boiling point

(i) below processing temperature and

(ii) equal to or greater than the normal boiling points of the low molecular weight drugs,

whereby said transdermal drug delivery system, subsequent to processing, is free of said solvents.

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